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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/341,590 07/13/99 LARSEN

B PPT-20479-US

HM12/0519

CHERYL H AGRIS  
PO BOX 806  
PELHAM NY 10803

EXAMINER

LUKTON, D

ART UNIT	PAPER NUMBER
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1653

8

DATE MAILED:

05/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/341,590

Applicant(s)

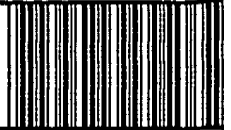
Due Larsen

Examiner

David Lukton

Group Art Unit

1653



☒ Responsive to communication(s) filed on Jan 24, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 DAYS month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

☒ Claim(s) 1-32, 37, 39, 41, 43, 45, 47, and 49 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-32, 37, 39, 41, 43, 45, 47, and 49 are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pursuant to preliminary amendment, claims 33-36, 38, 40, 42, 44, 46, 48, 50, 51 have been cancelled, and claims 1, 6, 7, 9, 13, 16, 20, 21, 32 amended. A subsequent paper (paper No. 6, filed 10/21/99) directed the amendment of claims 11, 12, 15, 18, 19, 24, 25. Claims 1-32, 37, 39, 41, 43, 45, 47, 49 are pending.

Paper No. 6 also directed several changes in the specification. As such, a **substituted specification is required**. (Applicants may, if preferred, choose to defer the submission of such until after the first action on the merits).

✱

A restriction is imposed, as set forth below. First, however, the following subgenera are defined.

G1: Z is  $(\text{Lys-Xaa})_m$  or  $(\text{Xaa-Lys})_m$  wherein m is 2 or 3

G2: Z is  $(\text{Lys-Xaa})_m$  or  $(\text{Xaa-Lys})_m$  wherein m is 4-7

G3: Z is  $(\text{Lys})_p\text{-(Xaa)}_q$  or  $(\text{Xaa})_q\text{-(Lys)}_p$ , wherein p is 1 or 2

G4: Z is  $(\text{Lys})_p\text{-(Xaa)}_q$  or  $(\text{Xaa})_q\text{-(Lys)}_p$ , wherein p is 3 or 4

G5: Z is  $(\text{Lys})_p\text{-(Xaa)}_q$  or  $(\text{Xaa})_q\text{-(Lys)}_p$ , wherein p is 5-14

G6: Z is  $(\text{Dbu})_n$  or  $(\text{Dpr})_n$  wherein n is 4-15

G8: Z comprises two or more lysine residues, but within "Z", there can be no more and no less than two lysines bonded together; Groups G1-G6 are excluded.

G9: Z comprises three or more lysine residues, but within "Z", there can be no more and no less than three lysines bonded together; Groups G1-G6 are excluded.

G10: Z comprises four or more lysine residues, but within "Z", there can be no more and no less than four lysines bonded together; Groups G1-G6 are excluded.

G11: Z comprises five or more lysine residues, but within "Z", there can be no less than five lysines bonded together; Groups G1-G6 are excluded.

G12: Z can contain any number of lysines (or no lysines), but there can be no more than 3 contiguous lysines within Z.

G13: Z must contain at least four lysines, and there must be at least 4 contiguous lysines within Z.

G14: Z can be anything that the claims permit, provided that G1-G11 are excluded.

G15: X is limited to enkephalin, Leu-enkephalin, Met-enkephalin, or endothelin, or vasoactive intestinal peptide, or substance P, or neurotensin, or endorphin, or insulin or gramicidin, or paracelsin or delta-sleep inducing peptide, or a modified or truncated analog thereof.

G16: X is limited to angiotensin-I, angiotensin-II, angiotensinogen, angiotensinogen (1-14) or vasopressin or oxytocin or calcitonin, calcitonin gene-related peptide, calcitonin gene-related peptide-II, or SEQ ID NO. 36), or a modified or truncated analog thereof.

G17: X is limited to parathyroid hormone (1-34) or parathyroid hormone related peptide or truncated erythropoietin analogs (including EMP-1) or atrial natriuretic peptide or brain

G19: X is limited to tachykinin or ACTH or cholecystokinin or corticotropin releasing factor or diazepam binding inhibitor fragment or FMRF-amide or leupeptin or sandostatin, or a modified or truncated analog thereof.

G20: X is limited to galanin or gastric releasing peptide (or -polypeptide) or gastric inhibiting polypeptide or glucagon or glucagon-like peptide -1 or -2 or exendin-3 or exendin-4, or a modified or truncated analog thereof.

G21: X is limited to LHRH or melanin concentrating hormone or melanocyte stimulating hormone or alpha-MSH or morphine modulating peptides or somatostatin or substance K or TRH or Kytorphin or melanostatin or hirulog or hirulog-1 or melanotan-II or thymosin alpha-1 or orniopressin or octreotide, or a modified or truncated analog thereof.

G22: X is limited to motilin or neurokinin-A or -B or neuromedin B, C, K, N or U or neuropeptide K or Y or PACAP or pancreatic polypeptide or peptide YY or peptide histidine methionine amide or secretin, or a modified or truncated analog thereof.

G23: X is limited to thrombopoetin analogs (including SEQ ID NO 14) or insulin-like growth factor I or II (including SEQ ID NOS. 15-20) or GHRP-6 or interleukin-II or beta-interleukin-I, beta-interleukin-II, or epidermal growth factor (20-31), or a modified or truncated analog thereof.

G24: X is limited to eptifibatide or endomorphin-1 or -2 or adrenomodulin or antiarrhythmic peptide or antagonist G or indolicin or osteocalcin or cortistatin-29 or cortistatin-14 or PD-145065 or PD-142893 or fibrinogen binding inhibitor peptide or leptin 93-105 or GR 83074 or Tyr-W-MIF-1, or a modified or truncated analog thereof.

G25: X can be anything the claims permit, provided that G15 - G24 are excluded.

G26: X is limited to the peptide recited in claim 37

G27: X is limited to the peptide recited in claim 39

G28: X is limited to the peptide recited in claim 41

G29: X is limited to the peptide recited in claim 43

G30: X is limited to the peptide recited in claim 45

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G31: X is limited to the peptide recited in claim 47

G32: X is limited to the peptide recited in claim 49

\*

Restriction to one of the 278 inventions that are defined on the accompanying spreadsheet  
is required under 35 U.S.C. §121.

Group	claims	Z	X
1	1-9, 13-15, 19, 20, 23, 24, 32	G1	G15
2	1-9, 13-15, 19, 20, 23, 24, 32	G1	G16
3	1-9, 13-15, 19, 20, 23, 24, 32	G1	G17
4	1-9, 13-15, 19, 20, 23, 24, 32	G1	G18
5	1-9, 13-15, 19, 20, 23, 24, 32	G1	G19
6	1-9, 13-15, 19, 20, 23, 24, 32	G1	G20
7	1-9, 13-15, 19, 20, 23, 24, 32	G1	G21
8	1-9, 13-15, 19, 20, 23, 24, 32	G1	G22
9	1-9, 13-15, 19, 20, 23, 24, 32	G1	G23
10	1-9, 13-15, 19, 20, 23, 24, 32	G1	G24
11	1-9, 13-15, 19, 20, 23, 32	G1	G25
12	1-9, 13, 19, 20, 23, 24, 32	G2	G15
13	1-9, 13, 19, 20, 23, 24, 32	G2	G16
14	1-9, 13, 19, 20, 23, 24, 32	G2	G17
15	1-9, 13, 19, 20, 23, 24, 32	G2	G18
16	1-9, 13, 19, 20, 23, 24, 32	G2	G19
17	1-9, 13, 19, 20, 23, 24, 32	G2	G20
18	1-9, 13, 19, 20, 23, 24, 32	G2	G21
19	1-9, 13, 19, 20, 23, 24, 32	G2	G22
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22	1-9, 13, 19, 20, 23, 32	G2	G25
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31	1-9, 16, 19, 20, 23, 24, 32	G3	G23
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35	1-9, 16-20, 23, 24, 32	G4	G16
36	1-9, 16-20, 23, 24, 32	G4	G17
37	1-9, 16-20, 23, 24, 32	G4	G18
38	1-9, 16-20, 23, 24, 32	G4	G19
39	1-9, 16-20, 23, 24, 32	G4	G20
40	1-9, 16-20, 23, 24, 32	G4	G21
41	1-9, 16-20, 23, 24, 32	G4	G22
42	1-9, 16-20, 23, 24, 32	G4	G23
43	1-9, 16-20, 23, 24, 32	G4	G24
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52	1-9, 16, 19, 20, 23, 24, 32	G5	G22
53	1-9, 16, 19, 20, 23, 24, 32	G5	G23
54	1-9, 16, 19, 20, 23, 24, 32	G5	G24
55	1-9, 16, 19, 20, 23, 32	G5	G25
56	1-8, 19-24, 32	G6	G15
57	1-8, 19-24, 32	G6	G16
58	1-8, 19-24, 32	G6	G17
59	1-8, 19-24, 32	G6	G18
60	1-8, 19-24, 32	G6	G19
61	1-8, 19-24, 32	G6	G20
62	1-8, 19-24, 32	G6	G21
63	1-8, 19-24, 32	G6	G22
64	1-8, 19-24, 32	G6	G23
65	1-8, 19-24, 32	G6	G24



66	1-8, 19-23, 32	G6	G25
67	1-9, 19, 20, 23, 24, 32	G7	G15
68	1-9, 19, 20, 23, 24, 32	G7	G16
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70	1-9, 19, 20, 23, 24, 32	G7	G18
71	1-9, 19, 20, 23, 24, 32	G7	G19
72	1-9, 19, 20, 23, 24, 32	G7	G20
73	1-9, 19, 20, 23, 24, 32	G7	G21
74	1-9, 19, 20, 23, 24, 32	G7	G22
75	1-9, 19, 20, 23, 24, 32	G7	G23
76	1-9, 19, 20, 23, 24, 32	G7	G24
77	1-9, 19, 20, 23, 32	G7	G25
78	1-9, 19, 20, 23, 24, 32	G8	G15
79	1-9, 19, 20, 23, 24, 32	G8	G16
80	1-9, 19, 20, 23, 24, 32	G8	G17
81	1-9, 19, 20, 23, 24, 32	G8	G18
82	1-9, 19, 20, 23, 24, 32	G8	G19
83	1-9, 19, 20, 23, 24, 32	G8	G20
84	1-9, 19, 20, 23, 24, 32	G8	G21
85	1-9, 19, 20, 23, 24, 32	G8	G22
86	1-9, 19, 20, 23, 24, 32	G8	G23
87	1-9, 19, 20, 23, 24, 32	G8	G24
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89	1-9, 19, 20, 23, 24, 32	G9	G15
90	1-9, 19, 20, 23, 24, 32	G9	G16
91	1-9, 19, 20, 23, 24, 32	G9	G17

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114	1-12, 19, 20, 23, 24, 32	G11	G18
115	1-12, 19, 20, 23, 24, 32	G11	G19
116	1-12, 19, 20, 23, 24, 32	G11	G20
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127	1-9, 20, 23, 24, 32	G14	G20
128	1-9, 20, 23, 24, 32	G14	G21
129	1-9, 20, 23, 24, 32	G14	G22
130	1-9, 20, 23, 24, 32	G14	G23

131	1-9, 20, 23, 24, 32	G14	G24
132	1-9, 20, 23, 32	G14	G25
133	26-31	G1	G15
134	26-31	G1	G16
135	26-31	G1	G17
136	26-31	G1	G18
137	26-31	G1	G19
138	26-31	G1	G20
139	26-31	G1	G21
140	26-31	G1	G22
141	26-31	G1	G23
142	26-31	G1	G24
143	26-31	G1	G25
144	26-31	G2	G15
145	26-31	G2	G16
146	26-31	G2	G17
147	26-31	G2	G18
148	26-31	G2	G19
149	26-31	G2	G20
150	26-31	G2	G21
151	26-31	G2	G22
152	26-31	G2	G23
153	26-31	G2	G24
154	26-31	G2	G25
155	26-31	G3	G15
156	26-31	G3	G16
157	26-31	G3	G17
158	26-31	G3	G18
159	26-31	G3	G19
160	26-31	G3	G20

167	26-31	G4	G16
168	26-31	G4	G17
169	26-31	G4	G18
170	26-31	G4	G19
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173	26-31	G4	G22
174	26-31	G4	G23
175	26-31	G4	G24
176	26-31	G4	G25
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190	26-31	G6	G17
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194	26-31	G6	G21
195	26-31	G6	G22
196	26-31	G6	G23
197	26-31	G6	G24
198	26-31	G6	G25
199	26-31	G7	G15
200	26-31	G7	G16
201	26-31	G7	G17
202	26-31	G7	G18

203	26-31	G7	G19
204	26-31	G7	G20
205	26-31	G7	G21
206	26-31	G7	G22
207	26-31	G7	G23
208	26-31	G7	G24
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221	26-31	G9	G15
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225	26-31	G9	G19
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229	26-31	G9	G23
230	26-31	G9	G24
231	26-31	G9	G25
232	26-31	G10	G15
233	26-31	G10	G16
234	26-31	G10	G17
235	26-31	G10	G18
236	26-31	G10	G19
237	26-31	G10	G20
238	26-31	G10	G21

239	26-31	G10	G22
240	26-31	G10	G23
241	26-31	G10	G24
242	26-31	G10	G25
243	26-31	G11	G15
244	26-31	G11	G16
245	26-31	G11	G17
246	26-31	G11	G18
247	26-31	G11	G19
248	26-31	G11	G20
249	26-31	G11	G21
250	26-31	G11	G22
251	26-31	G11	G23
252	26-31	G11	G24
253	26-31	G11	G25
254	26-31	G14	G15
255	26-31	G14	G16
256	26-31	G14	G17
257	26-31	G14	G18
258	26-31	G14	G19
259	26-31	G14	G20
260	26-31	G14	G21
261	26-31	G14	G22
262	26-31	G14	G23
263	26-31	G14	G24
264	26-31	G14	G25
265	37	G12	G26
266	37	G13	G26
267	39	G12	G27
268	39	G13	G27
269	41	G12	G28
270	41	G13	G28
271	43	G12	G29
272	43	G13	G29
273	45	G12	G30
274	45	G13	G30

275	47	G12	G31
276	47	G13	G31
277	49	G12	G32
278	49	G13	G32

Claims 1-25 and 32 are drawn to compounds, claims 26-31 are drawn to methods of making the compounds, and claims 37, 39, 41, 43, 45, 47, 49 are drawn to methods of using compounds. Thus, claim 1 encompasses 132 separate and distinct inventions.

Claim 25 is not grouped. In the event that applicants elect one of inventions 1-132, claim 25 will be joined with that group.

Inventions {133-264} and {1-132} are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). However, in the event that one of inventions 1-132 is elected and subsequently found allowable, claims drawn to a method of making the compounds will be rejoined for further examination. [*In re Ochiai* (37 USPQ2d 1127)]



- Group 31 encompasses claims 1-9, 16, 19, 20, 23, 24, 32. This group is limited to compounds wherein "X" is limited to thrombopoetin analogs (including SEQ ID NO 14), insulin-like growth factor I or II (including SEQ ID NOS. 15-20), GHRP-6, interleukin-II, beta-interleukin-I, beta-interleukin-II, epidermal growth factor (20-31), or a modified or truncated analog thereof; and "Z" is limited to  $(\text{Lys})_p\text{-(Xaa)}_q$  or  $(\text{Xaa})_q\text{-(Lys)}_p$ , wherein p is 1 or 2.
- Group 265 is limited to claim 37, wherein "X" is enkephalin, and Z can contain any number of lysines (or no lysines), but there can be no more than 3 contiguous lysines within Z.

The §371 status of the application is noted. However, as will become evident, claim 1 does not "define a contribution" over the prior art; as such, unity of invention is lacking.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound. To properly define a specie, the entire molecule must be described. This would include (but is not necessarily limited to) a selection of "Z" and "X".

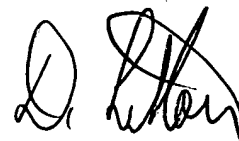
Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**DAVID LUKTON  
PATENT EXAMINER  
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